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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-FY-2018; Docket No. CDC-2018-0063]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS)

ACTION: Notice with comment period

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled "HIV prevention among Latina transgender women: Evaluation of a locally developed intervention". The collection is part of a research study designed to evaluate the efficacy of a locally developed and culturally congruent two-session Spanish-language small-group intervention, ChiCAS (Chicas Creando Acceso a la Salud [Chicas: Girls Creating Access to Health]), which provides combination HIV prevention services to

adult Hispanic/Latina transgender women at high risk for HIV infection.

DATES: CDC must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2018-0063 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

HIV prevention among Latina transgender women: Evaluation of a locally developed intervention - New - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC)

Background and Brief Description

The National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention is requesting approval for 20-months of data collection entitled, "HIV prevention among Latina transgender women: Evaluation of a locally developed intervention." The goal of this study is to evaluate the efficacy of ChiCAS (Chicas Creando Acceso a la Salud [Chicas: Girls Creating Access to Health]), a locally developed and culturally congruent two-session Spanish-language small-group combination intervention designed to promote consistent condom use, and access to and

participation in pre-exposure prophylaxis (PrEP) and medically supervised hormone therapy by HIV seronegative Hispanic/Latina transgender women who have sex with men.

The information collected through this study will be used to evaluate whether the ChiCAS intervention is an effective HIV-prevention strategy by assessing whether exposure to the intervention results in improvements in participants' health and HIV prevention behaviors. The study will compare pre- (baseline) and post-intervention (six-month) levels of HIV risk among participants who have received the intervention and participants who have not yet received the intervention (delayed-intervention group).

This study will be carried out in five metropolitan areas in North Carolina: Asheville, NC; Charlotte, NC; Research Triangle (metropolitan area of Greensboro, Winston-Salem and High Point NC); Raleigh, NC; and Wilmington, NC. The study population will include 140 HIV-negative Spanish-speaking transgender women. Participants will be adults, at least 18 years of age, self-identify as male-to-female transgender or report having been born male and identifying as female, and report having sex with at least one man in the past six months.

We anticipate participants will be comprised mainly of racial/ethnic minority participants under 35 years of age,

consistent with the epidemiology of HIV infection among transgender women.

Intervention participants will be recruited to the study through a combination of approaches, including traditional print advertisement, referral, in-person outreach, and through word of mouth. A quantitative assessment will be used to collect information for this study, which will be delivered at the time of study enrollment and again at six-month follow up. The assessment will be used to measure differences in sexual risk knowledge, perceptions and behaviors including condom use, PrEP use and use of medically supervised hormone therapy.

Intervention mediators, including healthcare provider trust and communication skills, self-reported health status and healthcare access, community attachment and social support will also be measured. All participants will complete the assessment at baseline and again at six-month follow-up after enrolling in the study. The intervention group will participate in ChiCAS after completing the baseline assessment and the delayed intervention group will participate in ChiCAS after completing the six-month follow up assessment.

We will also examine intervention experiences through in-depth interviews with 30 intervention group participants. The interviews will capture participants' general experiences with the ChiCAS intervention, as well as their experiences and

perceptions specific to the main study outcomes: PrEP knowledge, awareness, interest and use; condom skills and use; and hormone therapy knowledge, awareness, interest and use.

It is expected that 50% of transgender women screened will meet study eligibility. We expect the initial screening to take approximately four minutes to complete. The assessment will take 60 minutes (one hour) to complete and will be administered to 140 participants a total of two times. The interview will take 90 minutes (one and one-half hours) to complete and will be administered to 30 participants from the intervention group one time.

There are no costs to the respondents other than their time. The total estimated annualized burden hours is 172.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
General Public - Adults	Eligibility Screener	140	1	3/60	7
General Public - Adults	Contact Information	70	1	1/60	2
General Public - Adults	Assessment	70	2	1.0	140
General Public -	Interview	15	1	1.5	23

Adults					
Total					172

Jeffrey M. Zirger,

Acting Chief,

Information Collection Review Office,

Office of Scientific Integrity,

Office of the Associate Director for Science,

Office of the Director,

Centers for Disease Control and Prevention.

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